EXHIBIT 2

510(k) Summary

FIM Medical
30, rue Camille
69003 Lyon,
France
Fim@fim-medical.com
Tel + 33 (0)4 72 34 89 89
Fax + 33 (0)4 72 33 43 51

NOV 2 8 2008

January 10, 2008
Contact: Eric Derei, President

1. **Identification of the Device:**
   Proprietary-Trade Name: TABATABA® CO TESTER
   Classification Names: Carbon monoxide gas analyzer. Product Code CCJ, Regulation number 868.1430
   Common/Usual Name: CO Analyzer

2. **Equivalent legally marketed devices** K000962. PiCO Smokerlyzer, Bedfont Scientific Ltd.

3. **Indications for Use (intended use)** The TABATABA® CO TESTER is for the monitoring of Carbon Monoxide in exhaled breath. It is for use in smoking cessation programs and can be used for the screening of CO poisoning and smoke inhalation. It can also be used for ambient air monitoring. It is for use by health professionals..

4. **Description of the Device:** The TABATABA is a battery operated hand held carbon monoxide monitor for use as an aid in smoking cessation programs. The TABATABA is a complete tool for the prevention of the risks of active or passive smoking. It can be carried in the pocket or on the belt. The device is parametered by an internal menu (time, date, alarm threshold, measurement time of monitoring). It can be connected to a computer via an RS232 port, to record and analyze results.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench, standards, and clinical testing indicates that the new device is as safe and effective as the predicate devices.

6. **Comparison to predicate:**

Characteristic	K000962. PiCO Smokerlyzer, Bedfont Scientific Ltd.	TABATABA® CO TESTER
Indications for Use	For the monitoring of Carbon Monoxide in exhaled breath. It is for use in smoking cessation programs and can be used for the screening of CO poisoning and smoke inhalation. It can also be used for ambient air monitoring. It is for use by health professionals.	SAME
Construction	Hand held battery operated device	SAME
Display	LCD, 3 digit	LCD, 4 digit
Enclosure material	ABS	SAME
Mouthpiece	Polypropylene, replaceable.	SAME
Power source	2-AA Alkaline Batteries	SAME
CO Measurement	0-80 ppm and higher	0-500 ppm
Dimensions	120 x 75 x 45 (mm)	110 x 70 x 30 (mm)
Weight	200 gm.	170 gm.

7. **Conclusion**

After analyzing bench, laboratory, and clinical testing data, it is the conclusion of FIM Medical that the TABATABA® CO Tester as safe and effective as the predicate devices, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FIM Medical
C/O Daniel Kamm, P.E.
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

NOV 2 8 2008

Re: K080278
Trade/Device Name: TABATABA® CO Tester
Regulation Number: 21 CFR 868.1430
Regulation Name: Carbon Monoxide Gas Analyzer
Regulatory Class: II
Product Code: CCJ
Dated: November 17, 2008
Received: November 25, 2008

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____.

Device Name:____TABATABA® CO TESTER

Indications For Use:
The TABATABA® CO TESTER is for the monitoring of Carbon Monoxide in exhaled breath. It is for use in smoking cessation programs and can be used for the screening of CO poisoning and smoke inhalation. It can also be used for ambient air monitoring. It is for use by health professionals.

Prescription Use _X_ AND/OR Over-The-Counter Use____.
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080278